

ROUTING SLIP
GENERATED BY: HF-40
DATE: MAY 02, 2002

FDA CONTROL NUMBER: 02 2484

TRACER #: **OS #:**

DATE OF CORRESPONDENCE: 05/01/02

DATE INTO FDA: 05/02/02

TO: LESTER M CRAWFORD HF-1

FROM: DAVID ROSEN

SYNOPSIS: STAR SCIENTIFIC, INC.'S FILING OF COMMENTS CONCERNING ARIVA
CITIZEN PETITIONS (DOCKET NOS. 01P-0572 AND 02P-0075)

LEAD OFFICE: HFA-305

HOME OFFICE: HF-40

CONTACT/PHONE#: KRISTINA L GODDARD 301-827-2851

COPIES: HF-1 LESTER M CRAWFORD
 HF-2 MURRAY M LUMPKIN
 HF-10 LINDA A SUYDAM
 HF-40 LAJUANA D CALDWELL

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

| ASSIGNED TO | ACTION | DUE DATE |
|-------------------------------------|------------------|----------|
| ----- | ----- | ----- |
| HFA-305 BUTLERJ | NECESSARY ACTION | |
| REMARKS: ORIGINALS SENT TO HFA-305. | | |

MCDERMOTT, WILL & EMERY

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May 1, 2002

VIA HAND DELIVERY

Lester M. Crawford, D.V.M., Ph.D
Deputy Commissioner
Room 1471
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: Star Scientific, Inc.'s Filing of Comments
Concerning Citizen Petitions Docket Nos. 01P-0572 and 02P-0075

Dear Deputy Commissioner Crawford:

On behalf of our client Star Scientific, Inc., we filed the attached responses to Citizen Petitions filed by William Schultz, Esq. on behalf of the National Center for Tobacco Free Kids and Alan Bennett, Esq. on behalf of GlaxoSmithKline, concerning Star Scientific's compressed powdered hard tobacco product, Ariva™ Cigalett™ pieces.

Enclosed are courtesy copies of the responses for your review.

We firmly believe that Star Scientific's compressed powdered hard tobacco product Ariva™ falls outside of FDA's jurisdiction pursuant to the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120 (2000). The Ariva™ compressed powdered tobacco product is neither a food nor a food additive as defined under the Federal, Food, Drug and Cosmetic Act. The Petitions are without merit and should be denied.

Sincerely yours,



David L. Rosen

cc: Charles Fried, Esq.

Ambassador Gerald P. Carmen
The Carmen Group, Inc.

Patrick M. McSweeney, Esq.
McSweeney & Crump, P.C.

Paul L. Perito, Esq.
Chairman, President and COO
Star Scientific, Inc.

Robert E. Pokusa, Esq.
General Counsel
Star Scientific, Inc.